IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

LINDA ROLLINS	*	**CIVIL ACTION NO. 08-0387**
VERSUS	*	**JUDGE JAMES**
ST. JUDE MEDICAL, DIAG DIVISION, INC. formerly known as Daig Corporation; KENNSEY NASH CORPORATION; TYCO INTERNATIONAL; WYETH, INC., formerly known as American Home Production Corporation; TYCO HEALTHCARE GROUP LP, formerly known as Kendall Company	*	**MAGISTRATE JUDGE HAYES**

REPORT AND RECOMMENDATION

Before the undersigned Magistrate Judge, on reference from the District Court, is a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6) filed by Defendants St. Jude Medical, Inc., Kennsey Nash Corporation, Tyco International, Inc., Wyeth Inc., and Tyco Healthcare Group LP ("Defendants") (Document No. 16). The motion is opposed (Document No. 22). For reasons stated below, it is recommended that Defendants' motion to dismiss be **GRANTED IN PART** and **DENIED IN PART**.

PROCEDURAL AND FACTUAL BACKGROUND

On February 15, 2008, Linda Rollins ("Rollins") filed a complaint in the Fourth Judicial District Court, Ouachita Parish, alleging that she was injured during an angiogram performed by Dr. J. Michael Barraza on February 20, 2007. Rollins alleged that a medical device known as an Angio-Seal was used during the procedure and that there were "problems with the deployment of the Angio-Seal." She further alleged that after the procedure, she developed a large hematoma in her right groin and complained of pain in her leg, following which she returned to the hospital

and was rushed into emergency surgery, performed by Dr. Frank Sartor, for a right external iliac to distal common femoral bypass with a Gore-Tex graft and a thrombectomy. According to Rollins, this procedure did not clear the thrombus nor result in pulse down the foot being regained; therefore, a popliteal exploration was then done below the knee and selective thrombectomies were performed on the posterior tib and anterior tibial vessels. Rollins stated in her complaint that Dr. Sartor noted in his operative report that the Angio-Seal was sitting "in the middle of the artery" and that "there was a lot of damage to the common femoral artery." (State court complaint ¶ 11).

Rollins alleged that the Defendants were liable, based on negligence and/or strict liability, for the injuries she sustained in the above incident under the Louisiana Products Liability Act, La. R.S. 9:2800.51 *et seq*., on the following grounds: (1) unreasonably dangerous design; (2) unreasonably dangerous construction, composition, or manufacture; (3) failure to provide adequate warnings and/or instructions; (4) failure to warn of the dangers the Angio-Seal posed for individuals with small blood vessels; (5) failure to conform to express and/or implied warranties; (6) failure to appropriately train medical personnel in the proper use of the Angio-seal; (7) unreasonably dangerous marketing; (8) lack of informed consent; (9) redhibition; (10) failure to communicate to the medical community the possibility of complications discovered after the Food and Drug Association ("FDA") approval process ended; and (11) failure to manufacture the Angio-Seal in accordance with FDA specifications. She seeks damages for lost income; loss of future earning capacity - past, present, and future; medical expenses - past, present, and future; loss of enjoyment of life; mental anguish; emotional distress; disability; disfigurement and scarring; and mental and physical pain and suffering.

On March 24, 2008, Defendants removed Rollins' case to this Court based on diversity of

citizenship.[1] On April 21, 2008, Defendants filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) on the grounds that (1) Rollins' product liability claims are expressly preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), and (2) even assuming her claims are not preempted, Rollins' complaint fails to state a claim upon which relief may be granted because (1) it does not allege what the so-called "problems" with the Angio-Seal device were or how such problems caused her injury; (2) her claims for breach of warranty and redhibition are too general and redhibition is not a theory of recovery for personal injury; (3) a claim of lack of informed consent cannot be asserted against a product manufacturer; and (4) although a claim of failure to follow FDA manufacturing specifications is not necessarily preempted, Rollins' complaint failed to allege how the device was out of compliance with FDA specifications. Rollins subsequently filed a response to Defendants' motion to dismiss, in which she argues that her claim that Defendants failed to manufacture the device in accordance with FDA specifications was not preempted and that her allegations are sufficient to state a claim upon which relief may be granted. She also argued that she should be allowed to conduct discovery prior to her claims being dismissed.

After reviewing Defendants' motion to dismiss and Rollins' response, the undersigned issued an order noting that at least some of Rollins' claims were likely preempted and that

---

[1] On April 9, 2008, the undersigned granted Defendants leave to file an amended notice of removal identifying the citizenship of the parties that comprise Tyco Healthcare Group LP for the purpose of establishing diversity of citizenship. (Document No. 11). When Defendants' amended notice of removal failed to identify the citizenship of two partnerships by identifying the citizenship of their members, the undersigned granted Defendants leave to file a second amended notice of removal. (Document No. 24). Subsequently, on May 22, 2008, Defendants filed a second amended notice of removal which set forth the citizenship of these partnership members. As this second amended notice of removal established that no defendant shared the same citizenship as the plaintiff, the undersigned finds that this Court has subject matter jurisdiction over this action by way of diversity of citizenship.

portions of the complaint appeared vague, especially relating to the manner and type of the injuries Rollins had suffered. Because such deficiencies could be cured by amendment, the undersigned granted Rollins leave to file an amended complaint within thirty days of the order.

Rollins filed an amended complaint on June 30, 2008. In addition to much of the information contained in the original complaint, the amended complaint contains more specific information regarding how the Angio-Seal is used, its composition, and how it should be packaged. The amended complaint states that the Angio-Seal specifications require that when the device is packaged for shipping, the anchor must be in a vertical position within the bypass tube, neither extending beyond the end of the tube nor inserted deeply within it, and that when the Angio-Seal is inserted into a patient, the bypass tube – not the anchor – pushes open the hemostasis valve, the anchor is inserted into the artery, and the collagen plug is deposited on the outside of the artery wall. Rollins further alleges that on June 7, 2008, the Angio-Seal was recalled because "the devices were incorrectly packaged with a 0.038" guidewire verses the required 0.035" guidewire." (Amended Complaint ¶ 4E).

She states that, since January 1, 2008, seventy-one adverse event reports regarding the Angio-Seal device have been filed, and thirty-one of those reports contained the following statement: "No product was returned for evaluation. Review of the device history record was not possible since the lot number was unavailable." Rollins alleges that federal regulations require the manufacturer of devices such as the Angio-Seal to submit certain information in the adverse event reports, including a model number, catalog number, lot number, or other identifying number. She also alleges that she did not see an adverse event report regarding her procedure on the adverse event website and that Defendants' failure to file such a report would violate their mandatory reporting duties.

The amended complaint also provides a more detailed account of Rollins' alleged

injuries, including Dr. Sartor's diagnoses and the numerous procedures he performed. The complaint further states: "Indeed, Dr. Sartor found the Angio-Seal in the middle of the artery. It is thought that the anchor pierced the other side of the blood vessel and carried the Angio-Seal into the artery, with the Angio-Seal collagen causing the clot." (Amended Complaint ¶ 7D).

Rollins alleges that she discussed the Angio-Seal with Dr. Barraza after she was released from the hospital, at which time he told her there were problems with the device and that a company representative had flown to the Monroe, Louisiana, area to visit the hospital regarding these problems. She also states that, in answering interrogatories, Dr. Barraza stated that he properly placed the Angio-seal during Rollins' procedure and does not believe that he committed malpractice. The complaint further states as follows:

> Dr. Barraza also provided in his answers to Interrogatories that "previously I had placed hundreds, if not thousands of Angio-Seals with no complications. Unexpectedly, problems occurred with three (3) patients in one thirty (30)-day period, including Ms. Rollins."
>
> Dr. Barraza further stated that "he used hundreds, if not thousands of Angio Seals for at least five years prior to Ms. Rollins' procedure," and that "he is very experienced in successfully using the Angio-Seal device."
>
> Dr. Barraza further stated that the problem was with the deployment of the Angio-Seal device: "Dr. Barraza experienced deployment problems with the Angio-Seal device on three (3) separate occasions within approximate thirty (30)-day time frame. He contacted the manufacturer's representative and advised them of the problems. Dr. Barraza does not recall the representative's name or details. . . . Ms. Rollins case was one of these three noted."

(Amended Complaint ¶¶ 7G-I).

Rollins also added two claims to her original complaint: (1) Defendants have failed to meet packaging and manufacturing specifications set forth by the FDA and (2) Defendants have failed in their adverse event reporting requirements required by the FDA. In response to the amended complaint, Defendants argue that the amended complaint still fails to state a claim upon which relief may be granted in that Rollins again does not allege how the Angio-Seal deviated

from FDA manufacturing or packaging specifications or how it malfunctioned. Defendants further argue that Rollins has failed to allege any pertinent facts supporting a claim that they failed to comply with the FDA's adverse event reporting requirements or how this alleged failure caused Rollins' injuries.

LAW AND ANALYSIS

When considering a motion to dismiss, the Court must accept as true the well-pleaded factual allegations in the complaint, and construe them in the light most favorable to the plaintiff. *Johnson v. Dallas Indep. Sch. Dist.*, 38 F.3d 198, 205 (5th Cir. 1994), cert. denied, 514 U.S. 1017 (1995). "The district court may not dismiss a complaint under Rule 12(b)(6) unless it appears beyond a doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 102 (1957). "Nevertheless, minimal requirements [of pleadings] are not tantamount to non-existent requirements. The threshold may be low, but it is real--and it is the plaintiff's burden to take the step which brings his case safely into the next phase of the litigation." *Gooley v. Mobile Oil Corp.*, 851 F.2d 513, 514 (1st Cir. 1998). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1966 (2007) (citations omitted). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 1964-64.

Defendants argue, and Rollins appears to concede, that many of her products liability

claims are preempted. In *Gomez v. St. Jude Medical Daig Division, Inc.*, 442 F.3d 919 (5th Cir. 2006), the Fifth Circuit addressed the issue of whether numerous product liability claims regarding the Angio-Seal device, most of which are identical to those asserted by Rollins, were preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act. *Id.* at 928. With regard to the pertinent legal and regulatory framework, the court stated as follows:

> The Medical Device Amendments of 1976 classify medical devices into three categories based on the potential risk to the public. 21 U.S.C. § 360c(a)(1)(A)-(C); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). . . . Devices that present "a potential unreasonable risk of illness or injury" or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" are designated Class III. 21 U.S.C. § 360c(a)(1)(C). The Angio-Seal is a Class III medical device.
>
> Before a Class III device may be put on the market, the manufacturer must give the FDA "reasonable assurance" that the device is both safe and effective. 21 U.S.C. § 360e(d)(2). A manufacturer provides "reasonable assurance" through the PMA process. The PMA process requires the manufacturer to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Lohr*, 518 U.S. at 477, 116 S.Ct. 2240. Significantly, the FDA's involvement with the devices continues even after the PMA is complete. *See*, e.g., 21 C.F.R. § 814.80 (prohibiting the production or labeling of any device in a manner inconsistent with any conditions of approval specified in the approval order); 21 C.F.R. § 814.3a(d) (requiring an applicant to submit a supplemental application setting forth any proposed changes for FDA approval before implementing any changes).

Id. The court then stated that "[t]his circuit has held that the PMA process 'preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements" if the state-law claims impose "substantive requirements" different from or inconsistent with the federal law." *Id.* at 929 (citation omitted). In *Gomez*, the plaintiff asserted the following causes of action under the Louisiana Products Liability Act: unreasonably dangerous design, failure to warn of the dangers of the Angio-Seal, failure to warn the public of the dangers that the Angio-Seal posed for individuals with small blood vessels, failure to train

medical personnel to use the Angio-Seal properly, lack of informed consent, breach of express warranty, redhibition, failure to communicate to the medical community the possibility of complications discovered after the FDA approval process ended, failure to train physicians to address complications caused by the Angio-Seal, and failure to manufacture the device in accordance with FDA specifications. *Id.* at 926. The district court granted summary judgment to Defendants on all of the above claims, with the exception of the claim that the defendant failed to manufacture the Angio-Seal in accordance with FDA specifications, and the Fifth Circuit affirmed the district court's judgment, stating as follows:

> The district court properly granted summary judgment on Gomez's negligence claims that were based on aspects of the Angio-Seals' design, manufacture, and marketing that complied with the FDA-approved requirements. No negligence claims can be maintained as to devices that complied with the FDA requirements because success on those claims requires a showing that the FDA requirements themselves were deficient. These claims cannot be presented to a jury because, if successful, they would be inconsistent with the federal regulatory requirements. The district judge properly limited Gomez's negligence claims to a claim that the Angio-Seal used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications.

With regard to Gomez's claims regarding defective or negligent design of the Angio-Seal, the court found that "[t]he FDA studied the Angio-Seal design through the PMA process and approved it" and that "[t]o permit a jury to second-guess the Angio-Seal design by applying the Louisiana statutory standard for unreasonably dangerous design would risk interference with the federally-approved design standards and criteria." *Id.* at 930.

As for her claims for failure to warn and failure to train,[2] the Fifth Circuit stated:

---

[2] "Gomez . . . alleged state-law causes of action for failure to warn and failure to train, including a claim that because Kendall's clinical studies under-represented women, it failed to give adequate warnings of risks more likely to occur in women as a result of generally smaller blood vessels. *See* La.Rev.Stat. Ann. § 9:2800.57 (listing elements of inadequate warning claims). Gomez claimed that Kendall provided inadequate warnings; that Kendall should have

> The FDA approved Kendall's warnings and instructions for physicians contained in the Instructions for Use ("IFU") through the PMA process. That process required the FDA to approve clinical studies and evaluate the results, to specify the labeling requirements, and approve the label that issued. The FDA also approved the "Patient Guide" used to provide information and warnings to patients, again through the PMA process. Kendall's training requirements were also subjected to, and approved in, the PMA process. To permit a jury to decide Gomez's claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on Kendall. The district judge correctly found that Gomez's state-law claims that Kendall's labeling, warning, information, and training were inadequate or incomplete are preempted.

Gomez, 442 F.3d at 931. The Fifth Circuit also affirmed the district court's dismissal of Gomez's claim that the defendant failed to communicate to the medical community the possibility of complications discovered after the FDA approval process, stating as follows:

> Medical device manufacturers such as Kendall have ongoing obligations to report experience with the device to the FDA, and the FDA has plenary authority to amend the regulations and requirements it imposed relating to the device, up to and including removing it from the market. At the end of the PMA process leading to approval, the FDA issues conditions of approval requiring the manufacturer to meet ongoing reporting and other obligations. *See* 21 C.F.R. § 814.80; 21 C.F.R. § 814.3a(d). The record shows that after the FDA approved the Angio-Seal, Kendall submitted a proposed change to the warning label recognizing risk for patients with smaller veins, particularly females, and recommending additional procedures to mitigate this risk. Gomez's state-law claims related to Kendall's alleged failure to provide information obtained after the FDA approved the Angio-Seal risk the same interference with the federal regulatory scheme as her other claims and are preempted.

Id. at 931-32. Finally, with regard to Gomez's breach of express warranty claim, the Fifth

---

been required to provide more specific information about the Angio-Seal; that the consent forms should have required a physician to obtain a patient's specific, informed consent to the use of the Angio-Seal before its use; and that the material Kendall supplied to train in the use of the Angio-Seal were inadequate. Gomez also sought recovery under a theory of redhibition, which is Louisiana's equivalent to a breach of implied warranty claim. *See* La.Rev.Stat. Ann. § 2520 (West 1997)." *Gomez*, 442 F.3d at 931.

Circuit found that, because Gomez would have to prove that "the express warranty was untrue" in order succeed on that claim under Louisiana law, "[a] jury hearing Gomez's state-law breach of express warranty claim would have to decide whether Kendall's representations about the Angio-Seal were true." *Id.* at 932 (citing La.Rev.Stat. Ann. § 9:2800.58). Accordingly, because the representations made by the defendant were approved by the FDA, the Fifth Circuit held that the claim was preempted. *Id.*

With the exception of her claims for failure to manufacture and package the Angio-Seal in accordance with FDA specifications, failure to train, and failure to abide by reporting requirements, Rollins makes no attempt to differentiate the remainder of her claims from those found to be preempted in *Gomez* or to argue that such claims should be construed as allegations of violations of FDA regulations. Therefore, to the extent that they are based on actions by defendant which complied with FDA-approved standards and requirements, Rollins' claims based on (1) unreasonably dangerous/defective design, manufacture, construction/composition, and marketing; (2) failure to provide adequate warnings; (3) failure to provide adequate instructions; (4) lacked of informed consent; (5) redhibition; (6) failure to communicate to the medical community the possibility of complications discovered after the FDA approval process ended; and (7) failure to warn the public of the dangers that the Angio-Seal posed for individuals with small blood vessels, are preempted, and it is recommended that they be dismissed.[3]

[3] Defendants also argue that (1) Rollins' breach of warranty and redhibition claims fail as a matter of law because they are too general and because redhibition is not an available theory of recovery for personal injury under Louisiana law; and (2) Rollins' informed consent claim fails as a matter of law because an informed consent claim may not be asserted against a product manufacture. However, because Rollins has failed to allege any non-preempted breach of warranty, redhibition, or informed consent claim at this time, it is recommended that Defendants' motion to dismiss on these grounds be DENIED *without prejudice* to Defendants' right to seek

Insofar as Rollins contends that her claims may be impacted by underlying facts that must be developed through discovery,[4] the undersigned's recommendation of dismissal of the above claims should not be construed as extending to any claim other than one which is based on actions of Defendants that complied with FDA requirements; to the extent that Rollins were to claim that Defendants failed to comply with FDA requirements, such a claim would not be preempted. Thus, Rollins is free to seek leave to amend her complaint should any such additional facts regarding same come to light during discovery.

In addition, Rollins' claim that Defendants failed to manufacture the Angio-seal in accordance with FDA specifications is not preempted by the MDA amendments. In *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1011 (2008), the Supreme Court stated that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." (Citations omitted); *see also Gomez* 442 F.3d at 933 ("The district judge properly limited Gomez's negligence claims to a claim that the Angio-Seal used in her surgery was defectively

---

leave to amend to reassert such grounds at later date.

[4] Rollins cites *Stevens v. Pacesetter*, 2008 U.S. Dist. LEXIS 26880, *4 (D.S.C. Apr. 1, 2008), in which the court allowed discovery to proceed despite the fact that a motion to dismiss based on *Reigel* was pending and dismissed the plaintiff's complaint without prejudice to plaintiff's right to assert claims based on the defendant's failure to follow FDA regulations; *Strini v. Edwards Lifesciences Corp.*, 2008 U.S. Dist. LEXIS 24617, *4-9 (N.D.N.Y Mar. 26, 2008), in which the defendants argued that they should not be required to produce certain documents that were the subject of a discovery dispute because *Riegel* arguably denied many of the plaintiff's claims; in rejecting the defendant's motion, the court stated that "t]he documents ordered disclosed may reasonably lead to the discovery of evidence that the procedures followed by [the defendant] failed to comply with the procedures approved by the FDA and breached express warranties"; and a law review article discussing *Riegel* that cites a New York Times article that, according to Rollins, states "It takes discovery to prove violations of the federal regulations." See Thomas A. McCann, *Supreme Court Restricts State Tort Claims Against Federally-Approved Medical Devices*, 20 Loy. Consumer L. Rev. 348, 355 (2008).

manufactured because it did not comply with the FDA-approved specifications.").

Defendants contend that even assuming that Rollins' claim that they failed to abide by FDA specifications in packaging and manufacturing the Angio-Seal is not preempted, Rollins' amended complaint nonetheless fails to state a claim upon which relief may be granted in that it fails to allege how the Angio-Seal was defective, how it deviated from manufacturing or packing specifications, how problems with the deployment of the Angio-Seal were in any way related to the Angio-Seal itself or a defect therein, or how any specific defect in the Angio-Seal contributed to Rollins' injuries. They argue that Rollins' reference to Dr. Barraza's alleged statements that there were "problems" with the deployment of the Angio-Seal, that he experienced problems with three patients on one thirty-day period, and that he properly placed the Angio-Seal are conclusory allegations that do not equate to a specific claim of a defect.[5]

The undersigned finds, however, that Rollins has sufficiently alleged a claim based on Defendant's failure to manufacture and package the Angio-Seal in accordance with FDA specifications. As the Fifth Circuit has stated, in order to survive a 12(b)(6) motion, "the complaint must contain either direct allegations on every material point necessary to sustain a recovery . . . or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial." *Rios v. City of Del Rio*, 444 F.3d 417, 420-21 (5th Cir. 2006) (citation omitted).[6] In the case *sub judice*, Rollins has pled sufficient facts to

[5] Defendant's further argue that a problem with the deployment of a medical device relates to the use of the product rather than a defect in its assembly or composition, and that the law is well-settled that the occurrence of an incident or accident is not evidence of a defect.

[6] The court further stated:

> [A] statement of facts that merely creates a suspicion that the pleader might have a right of action' is insufficient. Dismissal is proper if the

meet this standard.

In order to recover based on a defective manufacturing claim under Louisiana law, a plaintiff must show the following: (1) defendant is a manufacturer of the product; (2) the product proximately caused the plaintiff's damage; (3) the damaging characteristic of the product rendered it "unreasonably dangerous"; and (4) the plaintiff's damage arose from a reasonably anticipated use of the product. Gomez, 442 F.3d at 932 (citing La.Rev.Stat. Ann. § 9:2800.54 (West 1997); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261 (5th Cir.2002)). "To prevail on a manufacturing defect claim under Louisiana law, the plaintiff must show that when the product left the manufacturer's control, it 'deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer.'" *Id.* at 933 (quoting La.Rev.Stat. Ann. § 9:2800.55).

Rollins alleges the following facts in her amended complaint in support of her claim that Defendants failed to manufacture and package the Angio-Seal in accordance with FDA specifications: (1) the Angio-Seal includes an anchor intended to keep any collagen from traveling to the inside of the artery; (2) Angio-seal specifications require that the device be packaged with the anchor in vertical position with the bypass tube, neither extending beyond the end of the tube nor inserted deeply within it; the bypass tube protects the anchor from damage during shipping and during surgery; (3) the Angio-seal has been the subject of two recalls, one of

---

> complaint lacks an allegation regarding a required element necessary to obtain relief. . . . The court is not required to 'conjure up unpled allegations or construe elaborately arcane scripts to' save a complaint. Further, 'conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.

Id. at 421 (citations omitted).

which was in June 2008 and was the result of the device being incorrectly packed with a 0.038" guidewire as opposed to the required 0.035" guidewire; (4) when the Angio-Seal is inserted into a patient, the bypass tube– not the anchor–pushes open the hemostasis valve, the anchor is inserted into the artery, and the collagen plug is deposited on the **outside** of the artery wall; (5) following Rollins' procedure, the Angio-Seal was found in the middle of Rollins' artery, and it is thought that the anchor pierced the other side of the Rollins' blood vessel and carried the Angio-Seal and collagen into the artery; (6) Dr. Barraza had deployment problems with the Angio-Seal in three patients in a thirty-day period, which resulted in his contacting the manufacturer and a company representative coming to the Monroe area to visit the hospital regarding the problems.[7] The complaint also provides a detailed allegation of the injuries allegedly suffered by Rollins.

Based on the above allegations, one can infer that Rollins intends to adduce evidence that the problem with the Angio-Seal to which the complaint refers was that the anchor of the Angio-Seal used in her procedure did not deploy properly, resulting in collagen entering her artery, due to its not being packaged and/or manufactured in accordance with FDA specifications. These

[7] Relying on Federal Rule of Civil Procedure 12(d), Defendants contend that Rollins' amended complaint is "replete with factual assertions that go far beyond the very few factual allegations in the original Petition which, if considered by the Court, convert Defendant's Rule 12 Motion to one for summary judgment." (Defendants Reply Memorandum p.5). Defendants then go on to argue that, even under the summary judgment standard, the facts Rollins alleges are either unsubstantiated and without record support or incorrect. However, facts alleged on the face of complaint, regardless of the source or veracity of those facts, are properly considered in a 12(b)(6) motion to dismiss, in which the inquiry is whether, assuming the facts alleged in the complaint are true, the plaintiff has stated a claim for which he or she is entitled to relief. All of the facts noted above as support for the undersigned's finding that Rollins stated a claim for relief for failure to follow FDA manufacturing and packaging specifications were stated in the complaint; therefore, Defendant's contention in this regard is without merit. So to is Defendants' contention that many of Rollins' factual assertions are "unsubstantiated" and that adverse event reports, absent proof of substantial similarity and temporal proximity to the incident at issue, are inadmissible. While possibly relevant to a summary judgment motion, these considerations are not relevant to a 12(b)(6) motion.

allegations are clearly sufficient to state a claim upon which relief may be granted, even without allegations regarding the model number, size, or lot number of the specific device.[8] *See Martinez v. Peterbilt Motors Co. Paccar, Inc.* 2004 U.S. Dist. LEXIS 22780 (W.D. Tex. Nov. 10, 2004) (finding that plaintiffs' allegation that windshield was defective because its placement deviated from specifications in unreasonably dangerous way and that the defect caused their injuries was sufficient to state a claim upon which relief could be granted for manufacturing defect). It is recommended that Defendants' motion to dismiss on this ground be DENIED.

With regard to her failure to train claim, Rollins argues that she has alleged that Defendants failed to abide by FDA regulations by "failing in [their] training requirements of the physician (Dr. Barraza)." Presumably in support of this claim, Rollins notes that she was "informed by the physician that training was not conducted." To the extent that this statement could be construed as a claim that Defendants failed to abide by the training requirements imposed by the FDA, as opposed to a claim that despite the fact that Defendant's followed the FDA's training requirements, such requirements were deficient in some way, it would not be

---

[8] Defendants contend that Rollins has failed to provide any information in the complaint concerning the size, model, or lot number of the Angio-Seal used in her procedure and that, without this critical information and evidence, there is no basis to any manufacturing defect claim. Rollins argues, and the undersigned agrees, that "Defendants[‘] 12(b)(6) motion is particularly specious in this case because it is Defendants who have the particular knowledge as to the control number of each unit, lot, or batch of finished devices that would enable Plaintiff to fill in the other details for trial." (Plaintiff's Supplemental Reply p. 4). Again, Rollins contends that she is not in possession of the device and the medical records that she has obtained do not identify the model number, size or lot number of the device. Rather, she contends, this information is in the defendant's possession. She does, however, state in her amended complaint, that the device used in her procedure had a catalog number of 610119.

Defendants also argue that the recall to which Rollins' refers occurred in June 2006 rather than June 2008 and therefore had nothing to do with Rollins' procedure. However, considering Rollins' allegations in their entirety, the fact that the date referred to in the amended complaint is incorrect does not affect the undersigned's conclusion that Rollins' has stated a claim for relief for failure to manufacture/package the Angio-Seal in accordance with FDA specifications.

preempted. However, although Rollins notes that Dr. Barraza allegedly never received any training in her opposition memorandum, no such allegation is included either her original or amended complaint.[9] In fact, there are no specific factual allegations regarding physician training in either complaint, only the conclusory allegations that (1) Defendants failed to appropriately train medical personnel in the proper use of the Angio-Seal and (2) failed to train physicians and to address complications caused by the Angio-Seal. Hence, Rollins has failed to plead any discernable non-preempted claim with regard Defendants' failure to train physicians in the use of the Angio-Seal.

Therefore, to the extent that Rollins' failure to train claim is based in any part on Defendants' actions that complied with the FDA training requirements, it is preempted. Accordingly, it is recommended that Defendants' motion to dismiss on this ground be GRANTED. However, because Rollins has indicated, albeit in her memorandum, a potentially non-preempted ground for her failure to train claim, it is recommended that she be granted ten (10) days in which to amend her complaint. If Rollins fails to do so within the time allotted, it is recommended that her failure to train claim be dismissed in its entirety.

Finally, with regard to Rollins' contention that Defendants failed to abide by FDA reporting requirements, it is somewhat unclear whether Rollins intends this allegation to be an independent cause of action, i.e. a claim that she could recover for her alleged injuries solely based on Defendant's alleged failure to abide by FDA reporting requirements. Rollins states in her amended complaint that since January 1, 2008, thirty-one of the seventy-one adverse event

[9] Moreover, in the undersigned's order allowing her leave to amend her complaint, Rollins was notified that many of her claims as they originally read were likely preempted. (See Document No. 23).

reports filed by Defendants state as follows: "No product was returned for evaluation. Review of the device history record was not possible *since the lot number was unavailable*." (Amended complaint ¶ 4F). She further states that federal regulations require a manufacturer to submit certain information in adverse event reports, including a model number, catalog number, lot number, or other identifying information.[10] Finally, Rollins states that she was unable to locate an adverse event report regarding her incident and Defendants' failure to file such a report would violate their reporting duties made mandatory by the FDA. Defendants argue that in approving the Angio-Seal, the FDA did not require Defendants to track the device from manufacturer to patient in accordance with 21 C.F.R. § 821;[11] rather, the Angio-Seal is subject only to the more

---

[10] The undersigned notes Rollins' cites 21 C.F.R. § 803.9(c) for the proposition that a manufacturer is required to submit the following information in an individual adverse event report: (1) brand name; (2) type of device; (3) manufacturer name and address; (4) operator of the device; (5) expiration date; (6) model number, catalog number, serial number, lot number, or other identifying number . . . . However, this requirement is actually set forth in 21 C.F.R. § 803.32(c), and applies to user facilities, not manufacturers, and only if the information is reasonably known to the user facility. 21 C.F.R. § 803.52(c), however, requires a manufacture to submit the above information in the adverse report to the extent the information is reasonably known to the manufacturer. Also, 21 C.F.R. § 803.1(a) requires manufacturers to "report deaths and serious injuries that [the manufacturer's] device may have caused or contributed to, . . . report certain device malfunctions, . . . and to establish and maintain adverse event files."

[11] 21 C.F.R. § 821.1(a) and (b) state as follows in pertinent part:

> (a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act), which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences; or the device is intended to be implanted in the human body for more than 1 year; or the device is a life-sustaining or life-supporting device used outside a device user facility. A device that meets one of these criteria and is the subject of an FDA order must comply with this part and is referred to, in this part, as a "tracked device."

general traceability requirements of 21 C.F.R. § 820.65.[12] They argue that Rollins has failed to allege in her complaint that Defendants have not complied with applicable requirements. Defendants further argue that even assuming they failed in their adverse event reporting requirements, Rollins has not alleged how such failure played any part in causing her alleged injuries.

With regard to Defendants' first argument, even assuming that the Angio-Seal's pre-market approval from the FDA did not expressly require that Defendants to track the Angio-Seal device from manufacturer to patient, but rather only to "maintain procedures for identifying with a control number each unit, lot, or batch of finished devices," 21 C.F.R. § 820.65, the undersigned finds that Defendants have failed to sufficiently demonstrate to the Court how this

---

> (b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. . . . Effective tracking of devices from the manufacturing facility . . . is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act).

[12] 21 C.F.R. § 820.65 states:

> Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

fact alone leads to the conclusion that Rollins fails to state a claim for relief; rather, this argument is more appropriately characterized as a defense to Rollins' claim that Defendants failed to abide by FDA reporting requirements and, therefore, should be raised on summary judgment.

However, the undersigned agrees with Defendants on their latter argument. Assuming that Rollins' intends her allegation that Defendants failed to include the lot number in adverse event reports regarding incidents unrelated to her own to be an independent cause of action, neither her amended complaint nor her opposition memorandum contains any allegation as to how this alleged failure, standing alone, caused her injuries. Under either a negligence or a strict liability theory, Rollins must prove causation in order to recover for her alleged injuries. *See Schexnayder v. Bunge Corp.*, 508 F.2d 1069 (5th Cir. 1975) ("[Strict liability] does not obviate the need to prove causation and damage."). Rollins also makes no attempt to demonstrate how any information sought and obtained through discovery would potentially reveal any evidence regarding causation.

Nonetheless, although the undersigned is not required to speculate, it is conceivable that the ground for Rollins' claim in this regard is that Defendants' failure to report the lot number in the adverse event reports led to the use of an Angio-Seal from a lot that should have been recalled prior to Rollins' procedure, especially given Rollins' allegation that Dr. Barraza had problems with the Angio-Seal with three patients in one thirty-day period. Therefore, although Rollins' allegations as currently pled fail to state a claim upon which relief may be granted, she is hereby GRANTED ten (10) days from the date of this Report and Recommendation in which to amend her complaint to adequately allege causation. In the absence of a timely amendment, and to the extent that Rollins may have intended this claim to be a separate cause of action, it is

recommended that Defendants' motion to dismiss on this ground be GRANTED.

As to her allegation that Defendants failed in their adverse event reporting requirements with regard to her individual procedure, Defendants have produced an adverse event report filed by St. Jude Medical regarding an incident involving the Angio-Seal device which occurred on February 20, 2007, which states as follows:

> **Event Description**
> It was reported following a cerebral angiogram that an angio-seal was used. The patient has a history of cerebral aneurysms [sic] and had experienced another small aneurysm. Post procedure, the patient experienced a large hematoma in the right groin and right leg pain. Later that same day, the patient underwent emergency surgical intervention. A right external iliac to distal common femoral bypass with a gore-tex graft was performed. A thrombectomy of the groin site failed to clear thrombus or regain pulses to the foot. Popliteal exploration behind the knee and selective thrombectomies were performed of the posterior and anterior tibial vessels. A vein patch was used to close the popliteal incision. The surgeon reported the angio-seal to be intra-arterial. The surgeon also reported that there was damage to the common femoral artery.

(Document No. 30 Ex. A). Rollins does not dispute that this is the adverse event report regarding her incident, and given that the date and the event description coincide almost word-for-word with the facts alleged in Rollins' complaint, it is clear that St. Jude did in fact file an adverse event report relating to Rollins' procedure. A court may take judicial notice of "adjudicative facts that are not subject to reasonable dispute."[13] *MacMillan Bloedel Ltd. V. Flintkote Co.*, 760 F.2d 580, 587 (5th Cir. 1985) (citing Fed. R. Evid. 201(b)). Moreover, "[i]n deciding a motion to dismiss the court may consider documents attached to or incorporated in the complaint and

[13] "A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b); *see also* Fed. R. Evid. 201(c) ("A court may take judicial notice, whether requested or not.").

matters of which judicial notice may be taken." *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996); *see also Horne v. Novartis Pharmaceuticals Corp.*, 541 F.Supp.2d 768, 777 (W.D.N.C. 2008) (stating that a court "may take judicial notice of and consider the public records of the FDA . . . without transforming this motion into a motion for summary judgment"). The adverse event report pertaining to Rollins' incident is available to the public on the FDA's website; therefore, the Court takes judicial notice of the fact that St. Jude filed an adverse event report regarding Rollins' incident with the Angio-Seal. Such judicial notice does not extend, however, to the adequacy of the contents of the report or the circumstances surrounding its filing, but only to its existence.

In addition, even if the Court were not to take judicial notice of the existence of the adverse event report, Rollins has again failed to allege how Defendants' failure to file such a report caused her injuries or any way in which Defendants could be held liable for her injuries based solely on such failure. Accordingly, to the extent that Rollins' allegation that the manufacturer failed to file an adverse event report pertaining to her incident is intended to be a separate cause of action, rather than a possible issue regarding evidentiary proof of facts, and to the extent that the allegation is based solely on the failure to file such a report, it should be dismissed. Accordingly, it is recommended that Defendants' motion to dismiss on this ground be GRANTED.

CONCLUSION

Based on the foregoing discussion, it is recommended that Defendant's motion to dismiss be **GRANTED** with regard Rollins' claims, **to the extent that such claims challenge actions on the part of Defendants that complied with FDA-approved standards and requirements**,

based on (1) unreasonably dangerous/defective design, manufacture, construction/composition, and marketing; (2) failure to provide adequate warnings; (3) failure to provide adequate instructions; (4) lacked of informed consent; (5) redhibition; (6) failure to train; (7) failure to communicate to the medical community the possibility of complications discovered after the FDA approval process ended; and (8) failure to warn the public of the dangers that the Angio-Seal posed for individuals with small blood vessels, and that these claims be **DISMISSED with prejudice**, subject to the plaintiff's right to seek leave to amend her complaint should discovery reveal a claim that defendants failed to comply with FDA regulations regarding any of the above, and that such failure caused injury to her. It is further recommended that, in the absence of an amendment by Rollins within the ten (10) days granted herein to allege a non-preempted failure to train claim, that Defendants' motion on this ground be **GRANTED**. It is further recommended that Defendants' motion to dismiss as it pertains to Rollins' allegation that Defendants failed to abide by FDA manufacturing and packaging specifications be **DENIED**.

In addition, to the extent that Rollins seeks to assert a separate cause of action based on Defendants' alleged failure to abide by FDA reporting requirements in failing to include the lot number in their adverse event reports, it is recommended that, in the absence of an amendment by Rollins within the ten (10) days granted herein to adequately allege causation, Defendants' motion to dismiss on this ground be **GRANTED**. Finally, it is recommended that Defendant's motion to dismiss as it pertains to Rollins' claim that Defendants failed to file an adverse event report pertaining to Rollins' procedure be **GRANTED.**

Under the provisions of 28 U.S.C. §636(b)(1)(c) and F.R.C.P. Rule 72(b), the parties have **ten (10) business days** from service of this Report and Recommendation to file specific,

written objections with the Clerk of Court. A party may respond to another party's objections within **ten (10) business days** after being served with a copy thereof. A courtesy copy of any objection or response or request for extension of time shall be furnished to the District Judge at the time of filing. Timely objections will be considered by the District Judge before he makes a final ruling.

A PARTY'S FAILURE TO FILE WRITTEN OBJECTIONS TO THE PROPOSED FINDINGS, CONCLUSIONS AND RECOMMENDATIONS CONTAINED IN THIS REPORT WITHIN TEN (10) BUSINESS DAYS FROM THE DATE OF ITS SERVICE SHALL BAR AN AGGRIEVED PARTY, EXCEPT ON GROUNDS OF PLAIN ERROR, FROM ATTACKING ON APPEAL THE UNOBJECTED-TO PROPOSED FACTUAL FINDINGS AND LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT JUDGE.

THUS DONE AND SIGNED at Monroe, Louisiana, this 23rd day of September, 2008

KAREN L. HAYES
U. S. MAGISTRATE JUDGE